Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application and annexes to the International Preliminary Examination Report.

1. A process for ~~preparing~~ purifying A1AT from A1AT-containing solutions or from other protein components, comprising the following steps:

   (a) subjecting an A1AT-containing solution to ion-exchange chromatography;

   (b) adding detergents and optionally a solvent for inactivating lipid-enveloped viruses;

   (c) followed by increasing the salt concentration to salt out the detergents.

2. The process according to claim 1, wherein said A1AT-containing solution has been obtained from blood plasma or its fractions, preferably from a reconstituted plasma fraction IV1 (Cohn), or is derived from a recombinantly or transgenically expressed A1AT preparation or a fermentation supernatant.

3. The process according to claim 1 ~~and/or 2~~, wherein ion-exchange chromatography is performed on an anion-exchange gel, preferably DEAE-Sepharose® or DEAE-Sepharose® Fast Flow.

4. The process according to ~~any of claims 1 to 3~~ claim 1, wherein said virus inactivation according to step (b) is effected with Triton X-100, Polysorbate 80

(Tween 80), TnBP and/or caprylic acid or caprylate, preferably at final concentrations of ≥ 0.1% (w/w) Triton and Tween 80, ≥ 0.03% (w/w) TnBP, ≥ 0.1 mM caprylic acid or caprylate, with an incubation time of ≥ 0.1 hours, preferably ≥ 1 hour, at ≥ 4 °C, especially at ≥ 15 °C.

5. The process according to ~~any of claims 1 to 4~~ claim 1, wherein the salt concentration of the solution is brought to ≥ 0.5 M in step (c) and particles formed thereby are preferably removed by filtration.

6. The process according to ~~any of claims 1 to 5~~ claim 1, wherein chromatography on hydrophobic chromatographic materials is performed.

7. The process according to ~~any of claims 1 to 6~~ claim 1, wherein a treatment of the A1AT-containing fraction with a material which contains heparin in an immobilized form (heparin gel) is performed.

8. The process according to ~~any of claims 5 to 7~~ claim 5, wherein a further virus inactivation step is performed afterwards, preferably pasteurization in the presence of ≥ 0.5 M sodium citrate, amino acids, sugars or mixtures thereof.

9. The process according to ~~any of claims 1 to 8~~ claim 1, wherein the ion strength of the solution is preferably reduced by ultra-/diafiltration.

10. The process according to ~~any of claims 1 to 9~~ claim 1, wherein a separation of virus particles is performed, preferrably by nanofiltration, preferably with filters having pore sizes of 15-20 nm.

11. The process according to ~~any of claims 1 to 10~~ claim 1, wherein the A1AT fraction obtained is stored as a liquid, frozen or freeze-dried preparation.

12. A1AT having a purity of > 90%, an activity of ≥ 0.8 PEU/mg in its active form, an IgA content of ≤ 1 mg/ml, a residual detergent content of < 50 ppm, especially < 10 ppm, and a monomer content of > 90%, based on the total amount of A1AT.

13. The A1AT according to claim 12, obtainable by a process comprising the following steps:

[-] (a) reconstitution of plasma fraction IV1 (Cohn);

[-] (b) anion-exchange chromatography on DEAE-Sepharose® Fast Flow;

[-] (c) optionally chromatography on a solid phase which comprises heparin in an immobilized form (heparin affinity chromatography);

[-] (d) optionally hydrophobic interaction chromatography (HIC);

[-] (e) virus inactivation with ≥ 0.1% (w/w) Triton/≥ 0.03% (w/w) TnBP with an incubation time of ≥ 1 hour at ≥ 15 °C;

[-] (f) addition of salt to increase the ion strength of the solution; and

[-] (g) removal by filtration of particles formed thereby.

14. The A1AT according to claim 13, wherein a further virus inactivation step is performed afterwards, preferably pasteurization in the presence of ≥ 0.5 M sodium citrate, amino acids, sugars or mixtures thereof.

15. The A1AT according to claim 13, wherein the ion strength of the solution is preferably reduced by ultra-/diafiltration.

16. The A1AT according to claim 13, wherein a virus and/or prion depletion or inactivation step is comprised, preferably a separation of virus particles by nanofiltration, preferably with filters having pore sizes of 15-20 nm.

17. The A1AT according to claim 13, wherein the A1AT fraction obtained is stored as a liquid, frozen or freeze-dried preparation.

18. A medicament containing an A1AT according to ~~any of claims 12 to 17~~ claim 12 as a sole active ingredient or in combination with anti-inflammatory agents, preferably steroids, NSAIDs.

19. Use of the A1AT according to ~~any of claims 12 to 17~~ claim 12 for preparing a medicament for the treatment of A1AT deficiency, degenerative phenomena of the lung, such as lung fibrosis and emphysema.